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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,795	04/04/2001	Staffan Folestad	1103326-0660	6487

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WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

TSOY, ELENA

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,795

Applicant(s)

FOLESTAD ET AL.

Examiner

Elena Tsoy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-20,22-25 and 27-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-20,22-25 and 27-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

1. Amendment filed on May 24, 2004 has been entered. Claims 3, 21 and 26 have been cancelled. Claims 1, 2, 4-20, 22-25, 27-53 are pending in the application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **Claims 1, 2, 7-9, 13-18, 20, 22-25, 27, 31, 32, 37-39, 41, 47, 48, 53** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996).

Patent '792 discloses a method for controlling the process of manufacturing a coating of a pharmaceutical product comprising monitoring simultaneously principal parameters relating to properties of the coating by performing a spectrometric measurement on said coating (See Claims 1, 20) wherein the step of performing the measurement on said coating is carried out on a sample within a coating vessel during the actual coating process (See Claim 10). The spectrometric measurement is performed by means of one of the spectrometric methods selected

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from the group consisting of: luminescence, fluorescence emission, and absorption in the UV, visible, or infra-red (IR) wavelength regions (See Claim 15), near-infrared spectrometry (See Claim 13), by a method based on Raman scattering (See Claim 14), or by means of a plurality of spectrometric measurements, each based on a different spectrometric method (See Claim 17).

Patent '792 fails to teach that the coating vessel is a fluidized bed and the sample of the pharmaceutical product is a particle so that spectrometric measurement is performed on a single pharmaceutical particle while coating within a fluidized bed.

As to claims 1, 2, 16, 20, 24, 25, 31, 37, 41, 48, 53, Drennen, III et al disclose a method and apparatus for monitoring the formation of a coating on a single article such as drug unit (particle) (See column 2, lines 1-5; column 3, lines 44-48), comprising the steps of: arranging the particle at a given spatial location in a fluidized bed by fluidizing the particle on an upwardly directed flow (See Fig. 2; column 4, lines 36-38); forming said coating on the particle by spraying the particle with a coating material through nozzle (See column 3, lines 65-67); and monitoring on-line (continuously) (See column 2, lines 65-67; column 3, lines 60-62) by a near-infrared spectrometric measurement on said coating during said step of forming said coating to obtain a measurement value of at least once principle parameter related to said coating such as amount of coating or coating thickness (See Abstract; column 2, lines 55-60). In other words, a secondary reference of Drennen, III et al is relied upon to show that a spectrometric measurement can be used for monitoring coating on a single pharmaceutical dosage unit (particle) such as pellet, tablet or capsule (See column 1, lines 16-20), while coating within a fluidized bed (See column 2, lines 44-50).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a method of Patent '792 for monitoring coating on a single pharmaceutical particle while coating within a fluidized bed with the expectation of providing the desired principal parameters relating to properties of the coating during forming the coating at any given spatial location since Drennen, III et al teach that a spectrometric measurement can be used for monitoring coating on a single pharmaceutical particle while coating within a fluidized bed.

As to claim 7, 9, 13-15, 32, 47, an apparatus of Drennen, III et al provides not only nondestructive inspection of a coated article to determine the extent of coating, it also provides means for determining **other characteristics**, such as granulation, **drying**, mixing and potency in drug layering (See column 1, lines 66-67; column 2, lines 1-5). In operation, a **computer** will have stored information regarding the desired extent of coating such that, as will be known to those skilled in the art, a comparison between the actual measured extent of coating and the desired extent of coating may be made in a **quantitative or qualitative** basis (See column 6, lines 21-33). Microprocessor means (control unit) may be employed so as to control operation of the inspection means as by controlling delivery of near infrared light, operation of the spectrometer means and, if desired, use of the information obtained from inspection in a servomechanism concept to **adjust or halt the coating system** (control of a wetting period) (See Figs. 9, 10; column 2, lines 38-43).

As to claim 8, it is the Examiner's position that the computer has an aggregate model for prediction of the influence of the control parameter on the principal parameter for a large number of the particles based on the functional relationship for the single particle *inherently* since

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Drennen, III et al teach that the inspection can be made on a single coated particle (See column 5, lines 5-12).

As to claims 22, 23, Drennen, III et al do not expressly show whether coating is carried out continuously or in batch process. However, it is the Examiner's position that monitoring the coating formation can be done by spectrometer means in either process.

As to claim 27, an apparatus of Drennen, III et comprises air distribution plate in the lower region with a flow of air within the apparatus so that air will flow between the particle and a measurement unit (shielding gas) (See Fig. 1; column 4, lines 35-45).

4. **Claims 4-6, 28-30, 35, 36** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Van Laethem (US 4,125,391).

Patent '792 in view of Drennen, III et al, as applied above, fails to teach that the step of forming the coating on the particle includes generating a single droplet of a fluid, and bringing said droplet to impinge on said particle.

Van Laethem teaches that the use of a single droplet discharge head of small dimensions allows easy control of the rate of supply of a coating material (See column 2, lines 28-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a single droplet discharge head of small dimensions instead of spray nozzles in Patent '792 in view of Drennen, III et al for supplying a coating material with the expectation of providing the desired easy control of the rate of supply of a coating material, as taught by Van Laethem.

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5. **Claims 10, 33, 42-44, 50** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Cody (US 5,420,681).

Patent '792 in view of Drennen, III et al, as applied above, fails to teach that the method comprises controlling property of the gas flow (Claims 10, 33, 42), such as a flow rate, a temperature or a content of a solvent (Claims 43, 44, 50).

Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating (See column 2, lines 27-30). It is the Examiner's position that mass flow depends on gas flow rate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have monitored an inlet air temperature, a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure in a method of Patent '792 in view of Drennen, III et al for coating particles with the expectation of providing the desired normal coating operation since Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating.

6. **Claims 11, 45** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Maguire et al (US 6,038,525).

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Patent '792 in view of Drennen, III et al, as applied above, fails to teach that spectrometric measurement can be used to control property of the particle (Claim 11) such as size, shape, density, porosity (Claim 45).

Maguire et al teach that Raman spectroscopy techniques may be used to monitor both the thickness and the chemical characteristics of a substrate (See column 4, lines 12-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used Raman spectroscopy techniques for monitoring a coating process of Patent '792 in view of Drennen, III et al since Maguire et al teach that Raman spectroscopy techniques may be used to monitor both the thickness and the chemical characteristics of the film.

7. **Claims 12, 34, 46, 52** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Van Laethem (US 4,125,391), and further in view of Patel et al (US 6,248,363).

Patent '792 in view of Drennen, III et al in view of Van Laethem, as applied above, fails to teach that the method comprises controlling property of the droplet (Claims 12, 34), such as size, generation rate, or concentration of a constituent (Claims 46, 52).

Patel et al teach that some critical success parameters in a fluidized bed coating of particles such as bed temperature, atomization, atomization fluid temperature, or droplet size, spray type, spray rate, rate of coating droplet solidification on particle surfaces, particle size, shape, etc., can be readily adjusted by one skilled in the art to achieve a satisfactory product fluidized bed coating (See column 50, lines 44-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have controlled some critical success parameters in a fluidized bed coating of particles such as bed temperature, atomization, atomization fluid temperature, or droplet size, spray type, spray rate, rate of coating droplet solidification on particle surfaces, particle size, shape, etc. in Patent '792 in view of Drennen, III et al in view of Van Laethem with the expectation of providing the desired satisfactory product fluidized bed coating, as taught by Patel et al.

8. **Claims 19, 40** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Woodruff (US 5,420,681).

Patent '792 in view of Drennen, III et al, as applied above, fails to teach that spectrometric measurement is performed by a method based on imaging spectrometer.

Woodruff teaches that imaging spectrometer may be used for measuring the thickness (See column 8, lines 15-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used imaging spectrometer for monitoring a coating process of Patent '792 in view of Drennen, III et al since Woodruff teaches that imaging spectrometer may be used for measuring the thickness.

9. **Claims 49, 51** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No.

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6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Van Laethem (US 4,125,391), and further in view of Cody (US 5,420,681).

Patent '792 in view of Drennen, III et al in view of Van Laethem, as applied above, fails to teach that the method comprises controlling property of the gas flow (Claim 49), such as a flow rate, a temperature or a content of a solvent (Claim 51).

Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating (See column 2, lines 27-30). It is the Examiner's position that mass flow depends on gas flow rate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have monitored an inlet air temperature, a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure in a method of Patent '792 in view of Drennen, III et al in view of Van Laethem for coating particles with the expectation of providing the desired normal coating operation since Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 2, 4-20, 22-25, 27-53 have been considered but are moot in view of the new ground(s) of rejection.

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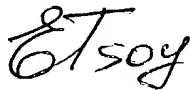
Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy
Primary Examiner
Art Unit 1762



July 20, 2004